UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

CIVIL ACTION NO. 21-10333-RGS

SHERI A. ENGREN

v.

JOHNSON & JOHNSON, INC., and ETHICON, INC.

MEMORANDUM AND ORDER ON
DEFENDANTS' MOTION TO DISMISS
FOR FAILURE TO STATE A CLAIM

September 17, 2021

STEARNS, D.J.

As treatment for certain abdominal and pelvic conditions, plaintiff Sheri A. Engren had implanted a polypropylene pelvic mesh designed, manufactured, and sold by defendants Johnson & Johnson, Inc., and Ethicon, Inc. By way of her Second Amended Complaint (SAC), Engren claims that the mesh was defective and unexpectedly eroded within five years, exacerbating her conditions. Defendants move to dismiss for failure to state a claim upon which relief may be granted. *See* Fed. R. Civ. P. 12(b)(6). For the reasons to be explained, the court will deny the motion in part and allow it in part.

## BACKGROUND

Engren had been diagnosed with severe stress incontinence and cystocele.[1] SAC ¶ 18. On September 26, 2013, Engren "underwent a procedure involving a pubovaginal sling using Prolene mesh, transvaginal bilateral repair using Prolene mesh, transvaginal anterior colporrhaphy using autologous tissue, and a cystoscopy using GYNECARE GYNEMESH™ PS" (Gynemesh PS). *Id.* Defendants manufacture, advertise, promote, and sell Gynemesh PS – a polypropylene[2] mesh product that is marketed and sold as a treatment for pelvic organ prolapse and stress incontinence. *Id.* ¶¶ 14-18. Engren underwent a revision surgery on March 22, 2018, at which time she was informed that she had suffered "eroded vaginal mesh and a recurrence of urinary urge incontinence." *Id.* ¶ 18. Engren complains that

[1] Stress incontinence is the unintentional loss of urine resulting from physical movement or activity, such as coughing, laughing, sneezing, running, or heavy lifting. *See* Mayo Clinic, https://www.mayoclinic.org/diseases-conditions/stress-incontinence/symptoms-causes/syc-20355727 (last visited Sept. 14, 2021). Cystocele, or anterior vaginal prolapse, occurs when the bladder drops from its normal position in the pelvis and pushes on the wall of the vagina. *See* Mayo Clinic, https://www.mayoclinic.org/diseases-conditions/cystocele/symptoms-causes/syc-20369452 (last visited Sept. 14, 2021).

[2] Polypropylene is "a thermoplastic 'addition polymer' made from the combination of propylene monomers." *Everything You Need to Know About Polypropylene (PP) Plastic*, https://www.creativemechanisms.com/blog/all-about-polypropylene-pp-plastic (last visited Sept. 14, 2021). It is currently one of the most produced plastics in the world. *Id.*

since the revision surgery, she has suffered from stress incontinence, severe bladder spasms, and general abdominal discomfort. *Id.*

Engren filed this diversity suit on February 6, 2021. She asserts claims for defects in manufacturing, design, and warnings (Count I-III); negligence (Count IV); breach of warranty (Count V); negligent misrepresentation (Count VI); and violation of Massachusetts's Consumer Protection Act, Mass. Gen. Laws ch. 93A (Count VII).

**DISCUSSION**

"The sole inquiry under Rule 12(b)(6) is whether, construing the well-pleaded facts of the complaint in the light most favorable to the plaintiffs, the complaint states a claim for which relief can be granted." *Ocasio-Hernandez v. Fortuno-Burset*, 640 F.3d 1, 7 (1st Cir. 2011). In most circumstances, the plaintiff need not demonstrate a "heightened fact pleading of specifics," but rather must present "only enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). Accordingly, facts that are "merely consistent with" a defendant's liability are inadequate. *Id.* Further, the recitation of the elements of a claim, "supported

by mere conclusory statements," is insufficient to establish facial plausibility. *Id.*

*Count I – Manufacturing Defect*

Defendants contend, and the court agrees, that Engren's manufacturing defect claim fails because she does not allege a specific deviation or flaw in the manufacturing process. Under Massachusetts law, a manufacturing defect occurs where "a particular product[,] rather than a line of products, is alleged to be defective because of negligence in the manufacturing process." *Smith v. Ariens Co.*, 375 Mass. 620, 626 (1978). Thus, "to establish a manufacturing defect, a plaintiff must demonstrate that there is a 'deviation from the design [that] rendered the product unreasonably dangerous and therefore unfit for its ordinary purposes.'" *Burnham v. Wyeth Labs., Inc.*, 348 F. Supp. 3d 109, 112 (D. Mass. 2018), quoting *Back v. Wickes Corp.*, 375 Mass. 633, 641 (1978).

Here, the SAC asserts that "[o]ne or more of the defects in the [Gynemesh PS] implanted in [Engren] are a result of improper or incorrect manufacturing processes." SAC ¶ 94. Without identifying a particular flaw or deviation, Engren's conclusory statement that the product was improperly

manufactured does not state a plausible claim for relief.[3] *See Iqbal*, 556 U.S. at 678; *see also*, *e.g.*, *Taupier v. Davol, Inc.*, 490 F. Supp. 3d 430, 440 n.6 (D. Mass. 2020) (dismissing manufacturing defect claim because the complaint was "devoid of allegations that the . . . mesh patch was manufactured in a manner that differed from its intended design").

*Count II – Design Defect*

In Engren's view, defendants' defective design of Gynemesh PS led to mesh erosion that necessitated the revision surgery to remove the mesh and left Engren with intractable abdominal discomfort. SAC ¶¶ 101-107. Defendants argue that Engren has failed to plead facts that plausibly link her claimed injuries to any alleged defective design.

Manufacturers have "the duty to design [their] product[s] so that [they are] reasonably fit for the purpose for which [they were] made." *Ariens Co.*, 375 Mass. at 623. "For a product to be defective, it must be 'made according to an unreasonably dangerous design' and does not meet a consumer's reasonable expectation as to its safety.'" *Niedner v. Ortho-McNeil Pharm., Inc.*, 90 Mass. App. Ct. 306, 312 (2016), quoting *Everett v. Bucky Warren, Inc.*, 376 Mass. 280, 290 (1978). To sketch a design defect, a plaintiff must

[3] Notably, defendants represent that they encouraged Engren to file a Third Amended Complaint to cure certain deficiencies in her allegations and that Engren declined to do so.

demonstrate "(1) the manufacturer's failure to exercise a reasonable degree of care under the circumstances; (2) proximate causation; and (3) injury and/or loss." *Geshke v. Crocs, Inc.*, 889 F. Supp. 2d 253, 261 (D. Mass. 2012), citing *Ulwick v. DeChristopher*, 411 Mass. 401, 408 (1991).[4]

Engren has pled sufficient facts to state a design defect claim. In the SAC, Engren avers that in 2008 – five years before her Gynemesh PS implant – the U.S. Food and Drug Administration (FDA) issued a Public Health Notification to transvaginal mesh manufacturers, including defendants, that there had been over 1,000 complaints of adverse events related to pelvic mesh products. SAC ¶ 30. In 2011 – two years before her procedure – the FDA issued a further "Safety Communication" that it had "conducted an updated analysis of adverse effects reported to the FDA and complications reported in the scientific literature and concluded that surgical mesh used in transvaginal repair of [p]elvic [o]rgan [p]rolapse was an area of 'continuing serious concern.'" *Id.* ¶ 31. The FDA determined that the incidence of serious complications was "not rare" and that "[m]any of the[se] serious

[4] A plaintiff has the further burden to establish the availability of a technologically feasible and practical alternative design that would have reduced or prevented the harm she suffered. *Evans v. Lorillard Tobacco Co.*, 465 Mass. 411, 428 (2013). However, the plaintiff need only convince a jury that the safer alternative design was feasible, "not that any manufacturer in the industry employed it or even contemplated it." *Haglund v. Philip Morris, Inc.*, 446 Mass. 741, 748 (2006).

complications required medical and surgical treatment and hospitalization." *Id.* Additionally, the FDA stated that there was no clear evidence that the use of surgical mesh for transvaginal repair of pelvic organ prolapse is "more effective than traditional non mesh repair of pelvic organ prolapse." *Id.* ¶ 32. In December of 2011, the American College of Obstetricians and Gynecologists (ACOG) and the American Urogynecologic Society (AUGS) likewise released a joint committee opinion identifying physical changes to the mesh inside the body as a serious complication, highlighting "increasing reports of vaginal pain associated with changes that can occur with mesh (contraction, retraction, or shrinkage) that result in taut sections of mesh," and remarking that "[s]ome of these women will require surgical intervention to correct the condition, and some of the pain appears to be intractable." *Id.* ¶ 34.

In light of the well-known reports of serious complications, one can reasonably infer that at the time of Engren's implant, defendants' design of Gynemesh PS was "unreasonably dangerous."[5] *Bucky Warren, Inc.*, 376

[5] Defendants, relying on nonbinding authority from other jurisdictions, argue that Engren's claim fails because she has not identified a "particular problem" in the design that caused her specific injury. *See Scism v. Ethicon, Inc.*, 2020 WL 1245349, at *2 (N.D.N.Y. Mar. 16, 2020); *Dolan v. Bos. Sci. Corp.*, 2021 WL 698777, at *2 (D. Minn. Feb. 23, 2020). Unlike these cases, Engren has identified mesh erosion, *see* SAC ¶ 18, as the particular problem.

Mass. at 290. These public health messages also provided defendants with sufficient notice of the defect such that defendants failed "to exercise a reasonable degree of care under the circumstances." *Geshke*, 889 F. Supp. 2d at 261. Viewed against the FDA's conclusion that polypropylene surgical mesh may not be more effective "than traditional non mesh repair of pelvic organ prolapse," SAC ¶ 32, Engren's suggestions of possible alternative designs – such as sutures, an autologous fascia lata and an autologous fascia sling, an allograft sling, and a sling with less polypropylene – are adequate to survive a motion to dismiss.

Engren has also pled sufficient facts that, taken as true, establish defendants' defective design of Gynemesh PS as the proximate cause of her injuries. Engren's allegation – that mesh erosion required a removal surgery and caused incontinence, bladder spasms, and abdominal discomfort, *see* SAC ¶ 18 – is consistent with the ACOG and AUGS joint committee opinion that mesh erosion, or "contraction," is a documented serious complication that in many cases requires "surgical intervention" and causes chronic pain and discomfort. *Id.* ¶ 34. Engren also notes that medical and scientific studies have concluded that mesh erosion and contraction are causally related to the polypropylene mesh products themselves and "do not implicate errors related to the implementation of the devices." *Id.* ¶¶ 53-54.

Taken together, Engren's claim crosses the dividing line from "merely consistent" to "plausible." *Iqbal*, 556 U.S. at 678.

*Count III – Failure to Warn*

Defendants maintain that because the SAC does not describe or disclose the content of any instructions or warnings that were given or should have been given by defendants to Engren's healthcare providers, Engren fails to establish that defendants' warnings were inadequate. The court agrees.

Under Massachusetts law, "a manufacturer can be found liable to a user of the product if the user is injured [because of] the failure of the manufacturer to exercise reasonable care in warning potential users of hazards associated with use of the product." *Laaperi v. Sears, Roebuck & Co., Inc.*, 787 F.2d 726, 729 (1st Cir. 1986). As a defense, the manufacturer may rely on the "learned intermediary" doctrine, which "provides that 'a . . . manufacturer's duty to warn of dangers associated with its product runs only to the physician; it is the physician's duty to warn the ultimate consumer.'" *Calisi v. Abbott Labs.*, 2013 WL 5441355, at *3 (D. Mass. Sept. 27, 2013), quoting *Cottam v. CVS Pharmacy*, 436 Mass. 316, 321 (2002).[6]

[6] This doctrine is justified by the reasoning that "the prescribing physician, as the 'learned intermediary' standing between the manufacturer and the consumer/patient, is generally in the best position to evaluate the potential risks and benefits of [the product's use] and to advise the patient accordingly." *Garside v. Osco Drug, Inc.*, 976 F.2d 77, 80 (1st Cir. 1992).

Courts use a burden-shifting framework "[t]o determine whether a plaintiff can make a prima facie case of negligence despite imposition of the learned intermediary rule." *Langlois v. Am. Med. Sys., Inc.*, 462 F. Supp. 3d 1, 3 (D. Mass. 2020). Under this framework, "the plaintiff carries the initial burden of producing sufficient evidence that the defendant manufacturer failed to warn of a non-obvious risk about which the manufacturer knew or should have known . . . ." *Garside*, 976 F.2d at 81.

Engren has failed to carry her initial burden. Although the court recognizes that Engren has not conducted discovery, the SAC does not "offer any description of the warnings and instructions that [defendants] provided or should have provided to" her healthcare providers. *Taupier*, 490 F. Supp. 3d at 447. Engren's allegation that defendants failed "to warn or instruct [her] and/or her health care providers of risks and complications," SAC ¶ 45, associated with her implant is "conclusory and insufficient to state a claim for negligent failure to warn even under the relatively lenient standard afforded to the pleadings at this stage of the litigation." *Taupier*, 490 F. Supp. 3d at 447.

*Count IV – Negligence*

Here, Engren essentially restates her product liability claims from Counts I-III. SAC ¶¶ 117-123. Because Count II will go forward, this

duplicative count will be dismissed so as to preclude dual relief for what ultimately is the same alleged wrong.[7] *See, e.g., Fitzgerald v. Commonwealth*, 2015 WL 924984, at *4 (Mass. Super. Ct. Feb. 26, 2015) (court saw "no reason to preserve substantively duplicative tort claims against [the] same defendants" given that the original tort claim would go forward).

*Count V – Breach of Warranties*

According to Engren, because her implant was unreasonably dangerous and defective, defendants breached their express and implied warranties that the product was safe, merchantable, and reasonably fit for its intended purposes. SAC ¶¶ 124-130. Both claims pass muster at this stage.

*(a) Breach of Express Warranty*

"Under Massachusetts law . . . an express warranty in a contract is a promise of a particular standard of performance, and it imposes on the warrantor an obligation to fulfill the promise made." *Sparks v. Fid. Nat'l*

[7] As defendants properly note in their motion to dismiss, because Massachusetts does not recognize product liability claims based on strict liability in tort, *see Swartz v. Gen. Motors Corp.*, 375 Mass. 628, 629 (1978), Counts I-III of Engren's SAC must be pursued under a theory of negligence. Further, defendants correctly point out that Engren's other "negligence" allegations – i.e., that defendants negligently tested, inspected, marketed, and packaged Gynemesh PS – are not recognized product liability theories under Massachusetts law.

*Title Ins. Co.*, 294 F.3d 259, 272 (1st Cir. 2002). Promotions or "[a]dvertisements can be express warranties." *Hebert v. Vantage Travel Serv., Inc.*, 444 F. Supp. 3d 233, 245 (D. Mass. 2020), citing *Hannon v. Original Gunite Aquatech Pools*, 385 Mass. 813, 822 (1982). "To establish a breach of express warranty claim . . . the plaintiff must demonstrate that the express warranty constituted a basis of the bargain between the seller and the buyer." *Sebago, Inc. v. Beazer East, Inc.*, 18 F. Supp. 2d 70, 102 (D. Mass. 1998). In so doing, the plaintiff must "prove that statements or representations made by the seller induced [her] to purchase the good and that [s]he relied on those statements or representations." *LePage v. E-One, Inc.*, 4 F. Supp. 3d 298, 312-313 (D. Mass. 2014).

Engren claims that defendants promoted Gynemesh PS "to physicians and patients as an innovative, minimally invasive procedure with *minimal local tissue reactions, minimal tissue trauma and minimal pain* while correcting vaginal prolapse, stress urinary incontinence, [and] pelvic organ prolapse." SAC ¶ 20 (emphasis added). In other words, by promoting Gynemesh PS's innovative nature and the "minimal" risks associated with using it, defendants warranted to Engren and her healthcare providers that the product was effective and safe. *See Hebert*, 444 F. Supp. 3d at 245. Further, Engren plausibly claims reliance on defendants' warranty in

deciding to implant Gynemesh PS, *see* SAC ¶ 126, as it stands to reason that Engren and her providers would have had serious misgivings about implanting a product that they thought was unreasonably dangerous and/or ineffective. *See LePage*, 4 F. Supp. 3d at 312-313.

*(b) Breach of Implied Warranty*

Pursuant to "the Uniform Commercial Code, . . . a warranty that goods . . . are merchantable is implied in a contract for their sale, and goods are merchantable if they are 'fit for the ordinary purposes for which such goods are used.'" *Evans v. Lorillard Tobacco Co.*, 465 Mass. 411, 422 (2013). "A seller breaches its warranty obligation when a product that is 'defective and unreasonably dangerous' . . . for the '[o]rdinary purposes' for which it is 'fit' causes injury." *Haglund v. Philip Morris, Inc.*, 446 Mass. 741, 746 (2006), quoting *Colter v. Barber-Greene Co.*, 403 Mass. 50, 62 (1988). "A product may be defective and unreasonably dangerous because of a manufacturing defect, a design defect, or a warning defect, that is, a failure reasonably to warn of the product's foreseeable risks of harm." *Evans*, 465 Mass. at 422.

Here, Gynemesh PS is a "good" covered under the Uniform Commercial Code, and – as previously discussed – Engren properly has stated a claim that Gynemesh's defective design proximately caused her injuries. Accordingly, Engren properly has stated a claim of breach of

implied warranty on the theory that the Gynemesh PS product implanted in Engren was "unreasonably dangerous because of . . . a design defect." *Evans*, 465 Mass. at 422.[8]

*Count VI – Negligent Misrepresentation*

Engren alleges that defendants negligently misrepresented Gynemech PS's "high risk of unreasonable, dangerous, adverse side effects" because defendants failed to disclose that the product "had not been adequately tested and found to be safe and effective for the treatment of incontinence and prolapse." SAC ¶¶ 131-135. Defendants contend, and the court concurs, that because Engren's SAC lacks any details about the specific content of any alleged representations and how these representations proximately caused her injury, Engren's claim is deficient.

To sketch a negligent misrepresentation claim, a plaintiff must allege that the defendant,

> "(1) in the course of [its] business, or in a transaction in which [it] had a pecuniary interest, (2) supplied false information for the guidance of others (3) in their business transactions, (4) causing and resulting in pecuniary loss to those others (5) by their justifiable reliance on the information, and that [it] (6) failed to exercise reasonable care or competence in obtaining or communicating the information."

[8] However, because Counts I and III of the SAC do not plausibly state a claim, Engren may not pursue a breach of implied warranty claim under the theories of manufacturing defect or failure to warn.

*Elec. Ins. Co. v. Great S. Fin. Corp.*, 2016 WL 1452338, at *6 (D. Mass. Apr. 13, 2016), quoting *DeWolfe v. Hingham Centre, Ltd.*, 464 Mass. 795, 799-800 (2013); *see also Fox v. F & J Gattozzi Corp.*, 41 Mass. App. Ct. 581, 587 (1996), citing Restatement (Second) of Torts § 552(1) (1977).[9]

For pleading purposes, "misrepresentation is considered a species of fraud." *Alt. Sys. Concepts, Inc. v. Synopsys, Inc.*, 374 F.3d 23, 29 (1st Cir. 2004). Although plaintiffs claiming misrepresentation usually are expected, pursuant to Fed. R. Civ. P. 9(b), "to specify the who, where, and when of the allegedly false . . . representation," *id.*, "courts are split on whether to apply [this] heightened pleading standard to claims of negligent misrepresentation." *Cabi v. Boston Children's Hospital*, 161 F. Supp. 3d 136, 164 (D. Mass. 2016). However, the First Circuit "reads Rule 9(b) expansively to cover associated claims where the core allegations effectively charge fraud." *N. Am. Catholic Educ. Programming Found., Inc. v. Cardinale*, 567 F.3d 8, 15 (1st Cir. 2009). "Thus, Rule 9(b) applies to claims of negligent misrepresentation where the *core allegation is fraud*, and likely does not

[9] Although the SAC alleges a wide spectrum of personal injuries resulting from the misrepresentations attributed to the defendant, including severe and permanent pain, suffering, permanent disability, and loss of the enjoyment of life, Massachusetts has not adopted Restatement (Second) of Torts § 311 (1965), which defines the tort of negligent misrepresentation to encompass *physical* injury. *See Gianocostas v. Interface Group-Mass., Inc.*, 450 Mass. 715, 727-728 (2008).

apply where the core allegation is negligence." *Gardner v. Simpson Fin. Ltd. P'ship*, 2012 WL 1109104, at *4 n.12 (D. Mass. Mar. 30, 2012) (emphasis added).

Here, there is little question that Engren's core allegations sound in fraud. Indeed, Engren devotes an entire section of the SAC – entitled "Fraudulent Concealment" – to defendants' alleged fraudulent behavior. SAC ¶¶ 87-93. Accordingly, Rule 9(b)'s heightened pleading standard governs. *See Gardner*, 2012 WL 1109104, at *4 n.12. Engren's claim falls short of this standard, as the SAC is devoid of facts describing "where" and "when" this "allegedly false . . . representation" occurred. *Synopsys, Inc.*, 374 F.3d at 29; *see Int'l Floor Crafts, Inc. v. Adams*, 477 F. Supp. 2d 336, 341 (D. Mass. 2007) ("[A] claimant alleging fraud or mistake must provide particulars as to the time, place and content of the alleged false or fraudulent misrepresentation.").

*Count VII – Violation of the Massachusetts Consumer Protection Act*

Finally, despite Engren's claim that defendants committed "unfair or deceptive acts" in violation of Massachusetts's consumer protection act, Mass. Gen. Laws ch. 93A, *see* SAC ¶¶ 136-139, the SAC's conclusory allegations both fail to establish the predicate elements for a Chapter 93A

claim and fall far short of satisfying the claim's heightened pleading requirements.

Chapter 93A proscribes "[u]nfair methods of competition and unfair or deceptive acts and practice in the conduct of any trade or commerce . . . ." Mass. Gen. Laws ch. 93A, § 2(a). To state a claim for a violation, a plaintiff must plead "(1) a deceptive act or practice on the part of the defendant; (2) an injury or loss suffered by the plaintiff, and (3) a causal connection between the defendant's deceptive act or practice and the plaintiff's injury." *Wagner v. Fed. Home Loan Mortg. Corp.*, 2020 WL 5868299, at *4 (D. Mass. Oct. 2, 2020). The "heightened pleading requirement" of Fed. R. Civ. P. 9(b) applies to Chapter 93A claims. *Munsell v. Colgate-Palmolive Co.*, 463 F. Supp. 3d 43, 52-53 (D. Mass. 2020).

Engren's claim is deficient under the heightened pleading standard because it does not specify "the time, place, and content of [any] alleged false representation." *United States ex rel. Gagne v. City of Worcester*, 565 F.3d 40, 45 (1st Cir. 2009). Moreover, aside from conclusory allegations, *see* SAC ¶¶ 87-93, 131-135, Engren fails to plead any facts that plausibly would demonstrate that defendants engaged in any "deceptive act or practice." *Wagner*, 2020 WL 5868299, at *4. Thus, this claim too will be dismissed.

**ORDER**

For the foregoing reasons, defendants' motion to dismiss the SAC is DENIED-IN-PART as to Count II and to Count V in so much as it alleges the breach of express warranty and the breach of implied warranty based on a design defect. The motion is ALLOWED as to all other claims.

SO ORDERED.

/s/ Richard G. Stearns
UNITED STATES DISTRICT JUDGE